



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0147]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products and Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collections in the guidances for industry and FDA staff entitled “Guidance for Industry and Food and Drug Administration Staff on Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products” and “Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions.”

DATES: Submit either electronic or written comments on the collection of information by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper

performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry and Food and Drug Administration Staff on Section 905(j) Reports:  
Demonstrating Substantial Equivalence for Tobacco Products--(OMB Control Number 0910-0673) (Extension)

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) ([Pub. L. 111-31](#)) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding a new chapter granting FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Section 905(j) of the FD&C Act ([21 U.S.C. 387e\(j\)](#)) authorizes FDA to establish the form for the submission of information related to substantial equivalence (SE). In guidance documents issued under the Good Guidances Practices regulation ([21 CFR 10.115](#)), FDA provides recommendations intended to assist persons submitting reports under section 905(j) of the FD&C Act and explains, among other things, FDA’s interpretation of the statutory sections related to substantial equivalence.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
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Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Full SE 905(j)(1)(A)(i) and 910(a)	75	1	75	300	22,500
Product Quantity Change SE Report	125	1	125	87	10,875
Same characteristics SE Report	100	1	100	47	4,700
Totals					38,075

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA has based these estimates on information it now has available from interactions with the industry, information related to other regulated products, and FDA's expectations regarding the tobacco industry's use of the section 905(j) pathway to market their products. Table 1 describes the annual reporting burden as a result of the implementation of the SE requirements of sections 905(j) and 910(a) of the FDC Act ([21 U.S.C. 387j](#)(a)). Based on current information, FDA now estimates that it will receive 300 section 905(j) reports each year. Of these 300 reports, FDA estimates that 75 of these reports will be "full" SE reports that take a manufacturer approximately 300 hours to prepare. Under the newly issued guidance entitled, "Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions," FDA is recommending that certain modifications might be addressed in either a "Same Characteristics SE Report" or "Product Quantity Change Report." FDA estimates that it will receive 100 Same Characteristics SE Reports and that it will take a manufacturer approximately 47 hours to prepare this report. FDA estimates that it will receive 125 Product Quantity Change SE Reports and that it will take a manufacturer approximately 87 hours to prepare this report. Therefore, FDA estimates the burden for submission of SE information will be 38,075 hours.

Dated: February 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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